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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,197	08/14/2001	John R. Reynolds	41530/28293	1200

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EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/01/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/929,197

Applicant(s)

REYNOLDS ET AL.

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 6
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Examiner acknowledges receipt of declaration and drawing filed 10/11/01; power of attorney filed 01/16/02; IDS filed 01/29/02 and 06/21/02.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 17-26 and 38-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 makes reference to Figure 1 and a claim must stand alone to define the invention and express reference to a Figure or drawing is not permitted. See Ex parte Fressola.

Claims 38 and 37 are indefinite because the claims are unclear as to what the claims what to convey. Both claims recite "wherein the reaction wherein the" and it is not clear what the claims mean.

3. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for failing to recite process or method steps and thus lacks active process or method steps.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1-6, 10-14, 16-31 and 36-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Kinlen ("Controlled Drug And Biomolecule Release from Electroactive Host Polymer System," presented at American Chemical Society Meeting, Anaheim, California, March 1999).

Kinlen discloses electroactive polymer, which is a polypyrrole /poly(styrene sulfonate) (PP/PSS) system for delivery of cationic biomolecules such as dopamine, epinephrine (catecholamines) and metaproterenol; which is a polypyrrole/ATP system and which is a polypyrrole/salicylate system for delivery of anionic biomolecules (page 307). Exhibition of non-Faradaic release profile is a property of the electrode and a prior art electrode that meets the limitations of the instant electrode would inherently have the same property since the property of the electrode cannot be separated from the electrode. Kinlen meets the limitations of the claims.

6. Claims 1, 3-15, 17, 19-24, 27-34, 36, 37, 39, 41 and 43-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhou et al. ("Electrochemically controlled binding and release of protonated dimethyldopamine and other cations from poly (N-methylpyrrole)/polyanion composite redox polymers," J. Electroanalytical Chem., 261 (1989) pp 147-164).

Zhou discloses a composite polymer of poly(N-methylpyrrole)/poly(styrenesulfonate) (PMP<sup>+</sup>PSS<sup>-</sup>) that is prepared by polymerization and the composite polymer is used for the release of dopamine or dimethyldopamine; electropolymerization can be carried out at constant potential or constant current (abstract and pages 147-163). Non-Faradaic response is a property of the composite polymer and thus meets the limitation. Zhou meets the limitations of the claims.

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7. Claims 1-3, 5-8, 10, 11, 13-15, 17-19, 21-23, 27-29, 32, 33, 35-38, 40, 42 and 44-50 rejected under 35 U.S.C. 102(b) as being anticipated by Pyo et al. ("Electrochemical Stimulated Adenosine 5'-Triphosphate (ATP) Release through Redox Switching of Conducting Polypyrrole Films and Bilayers," Chem. Mater., vol. 8, (1996) pp. 128-133.

Pyo discloses electroactive polymer comprising polypyrrole/polyanion composite polymer and the composite polymer is selected from polypyrrole/ATP (PP/ATP) and poly(N-methylpyrrole (PNMP)/with various dopant anions. Pyo discloses a bi-layer structure where the PP/ATP is an inner layer and the PNMP/with various dopant anions as outer layer such as chloride and heparin that is dominantly cation transporter. See abstract and pages 128-133. Exhibition of non-Faradaic release profile is a property of the electrode and a prior art electrode that meets the limitations of the instant electrode would inherently have the same property since the property of the electrode cannot be separated from the electrode. The teachings of Pyo meet the limitations of the claims.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Miller et al. (US 4,585,652) discloses controlled release delivery system that comprises electrochemically recyclable polymeric electrode upon which is loaded bioactive counter ions (abstract and column 2, lines 26-36). The bioactive counter ions are anionic or cationic or neutral (column 5, line 47 to column 6 line 35) and the polymeric body can have cationic sites (claim 3) or anionic sites (claim 5). Poly(pyrroles), substituted polythiophenes, poly(thiophenols), poly(aromatics), polyacetylenes are examples of polymers that can be employed in Miller (column 4, lines 15-68).

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*Claim Objections*

9. Claim 6 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Suggestion:


In line 2 of claim 31, it is suggested that the parenthesis be deleted and ---selected from--- be inserted after catecholamines.

10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara   
Patent Examiner  
Tech. Center 1600